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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,615	02/15/2002	Joseph C. Cauthen III	8442.0002-02	2841

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,615

Applicant(s)

CAUTHEN, JOSEPH C.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004 and 26 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-12, 14-16 and 20-22 is/are rejected.
- 7) ☒ Claim(s) 1-7 and 17-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 2/17/04 has been entered. The changes to the claims have been approved by the examiner. Claim 13 has been canceled. The claims being considered for further consideration on the merits are 1-12 and 14-22. The examiner acknowledges that an amended Figure 9 was submitted with the amendment to overcome a drawing objection. However, this drawing is currently not available to the examiner for review and is in the process of being made available. Approval or disapproval of the drawing correction will be made in the office action. No action is required by the applicant on this matter.

Response to Arguments

2. Applicant's arguments, see pages 7-8 and 9-11, filed 2/17/04, with respect to the rejection(s) of claim(s) 1-22 under 35 U.S.C. 112, first paragraph, claims 8-12, 15 and 20-22 under 35 U.S.C. 102(e), and claims 13, 14 and 16 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, new ground(s) of rejections are made in view of Kuslich (USPN 5,571,189), Ferree (USPN 6,245,107) and Bao et al. (USPN 6,224,630).

Specification

3. The substitute specification filed 5/26/04 has been entered. All previous amendments to the specification have been approved by the examiner.

Claim Objections

4. The objection to claim 17 set forth in the office action mailed 8/29/03 is maintained.

Claim 17 is objected to because on line 3, either "a trapezoid" should be changed to --trapezoidal-- or "circular and curved" should be changed to --circle and curve--.

5. Claim 21 is objected to because on line 1, "The therapeutic" should be changed to --A therapeutic--. This appears to be a transcription error.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 10 recites the limitation "said internal cavity" in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 10 should be dependent on claim 9 rather than on claim 8.

8. Claim 14 recites the limitation "said biocompatible fluid" in line 2. There is insufficient antecedent basis for this limitation in the claim because it is dependent on canceled claim 13. It appears that claim 14 should be dependent on claim 16, and will be interpreted to be so for examination purposes.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 8-12, 15, 16 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuslich (USPN 5,571,189 as cited in applicant's IDS).

Kuslich discloses a therapeutic device capable of treating a spinal disc annulus having an aperture with all the elements of claim 21. See Figures 4, 5, 8-10 and column 7, lines 8-20 and 41-53 for the device (40) comprising a biocompatible material for placement in (Figure 5) and across (Figure 10) the aperture (46) such that the material forms a bridge (when fill opening 48 is closed by knot 58 shown in Figures 10 and 18). The equatorial band (42) portion of the device (40) opposes the annular wall (column 6, lines 62-65) and is made up of multiple layers of the fabric that forms the device (40) (column 10, lines 7-9). See column 7, lines 8-20 for the fabric that forms the device (40) allowing the ingrowth and through-growth of blood vessels and fibrous tissue and bony trabeculae. The equatorial band (42), opposing the annular wall, will therefore inherently provide a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus.

Claims 8 and 9, see column 6, lines 57-60 for the device (40) comprising a bladder (bag) comprising a material enclosing an internal cavity.

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Claim 10, see Figure 5 and columns 6-7, lines 67-4 for the internal cavity being empty.

Claim 11, see column 7, lines 21-22 for the material comprising a thin flexible biocompatible material.

Claims 12 and 15, see column 7, lines 8-20 and 40-52 for the material comprising a semi-permeable material or an impermeable material (solid material with perforations added).

Claim 16, see column 7, line 10 for internal cavity containing a biocompatible fluid.

Claims 20 and 22, see column 7, lines 8-20 for the material facilitating the regeneration of disc tissue. The fabric material provides as means for fixating the device to the annulus because it allows for the ingrowth of fibrous tissue.

11. Claims 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (USPN 6,245,107 as cited in applicant's IDS).

Ferree discloses a therapeutic device for treating a spinal disc annulus having an aperture with all the elements of claim 21. See Figure 15C and column 6, lines 5-11 for the device (patch) comprising a biocompatible material for placement in and across the aperture such that the material forms a bridge providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus.

Claim 20, see column 6, lines 7-9 for material facilitating the regeneration of disc tissue.

Claim 22, see column 6, lines 11-13 for means for fixating the device to the annulus.

12. Claims 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Bao et al. (USPN 6,224,630 as cited in applicant's IDS).

Bao et al. discloses a therapeutic device for treating a spinal disc annulus having an aperture with all the elements of claim 21. See columns 2-3, lines 58-7 for the device comprising a biocompatible material for placement in and across the aperture (columns 7-8, lines 63-9) such that the material forms a bridge providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus.

Claim 20, see columns 5-6, lines 30-47 for examples of materials that facilitate the regeneration of disc tissue.

Claim 22, see column 14, lines 22-24 for means for fixating the device to the annulus.

Allowable Subject Matter

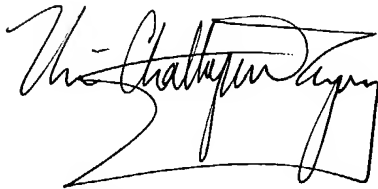
13. Claims 1-7 and 17-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 10 and 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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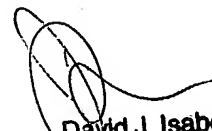
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner